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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,158	03/15/2001	Carol O. Cowing	LANCELL.002CP1	5364

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EXAMINER
CANELLA, KAREN A

ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/809,158	COWING, CAROL O.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,3-11,13-19,21-24,27-31,42,51-53 and 55-57* is/are pending in the application.

4a) Of the above claim(s) *4,5,7,9,10,37 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) *17,19 and 51* is/are allowed.

6)☐ Claim(s) *1, 3, 6, 8, 11, 13-16, 18, 21, 22, 23 24,27-31, 52, 53, 55* is/are rejected.

7)☐ Claim(s) *57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 2, 12, 20, 25, 26, 32-36, 38-41, 43-50 and 54 have been canceled. claims 1, 3, 8, 11, 13, 15, 17, 19, 23 and 24 have been amended. Claims 4, 5, 7, 9, 10, 37 and 42 remain withdrawn from consideration. Claims 1, 3, 6, 8, 11, 13-19, 21-24, 27-31, 51-53 and 55-57 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action

Claims 1, 3, 6, 8, 11, 13-16, 18, 21, 22, 23 and 27-31are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .Applicant has amended claim 1 to incorporate the limitation "wherein said lipophilic molecule....does not induce contact dermatitis". However, this limitation was not present in the application as filed, and the instant claims are rejected as containing new matter.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Bauer et al (U.S. 4,036,952). Claim 24 is drawn to a method for vaccinating a mammal comprising introducing into said mammal an effective dose of an antigen or epitope thereof and administering to the mammal a topical treatment in an amount sufficient to increase the number of antigen-bearing dendritic cells in a lymphoid organ wherein introducing the antigen and administering the treatment are performed independently in any order and wherein the antigen or epitopes thereof are introduced into the mammal by a transfer of cells.

Bauer et al discloses a method for vaccinating a mammal comprising the topical application of inactivated virus or bacteria (column 2, lines 38-55). Thus the disclosure of Bauer et al anticipates the instant invention wherein the topical treatment and the introduction of the antigen are performed at the same time. Bauer et al do not specifically disclose that the

method would be sufficient to increase the number of antigen-bearing dendritic cells in a lymphoid organ, however, this would be an inherent property of a successful vaccination.

The rejection of claims 55 and 56 under 35 U.S.C. 102(b) as being anticipated by King et al (Vaccine, 1987, Vol. 5, pp. 234-238) is maintained for reasons of record. Applicant argues that King et al do not anticipate all the limitations of the claimed invention because King et al fails to teach the number of dendritic cells within a lymphoid organ. this has been considered but not found persuasive because the increase of dendritic cells within a lymphoid organ would be inherent in a successful vaccination.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Paul et al (Vaccine Research, 1995, Vol. 4, pp. 145-164) as evidenced by Roitt et al, (Immunology (text), 1993, pages 8.3-8.4) is maintained for reasons of record. claim 20 is also rejected for the same reasons of record.. Paul et al disclose a method for vaccinating a mammal against an antigen comprising the topical administration of an antigen encapsulated in tranfersomes. Paul et al disclose that the encapsulated protein traverses the stratum corneum by means of the ultra deformable submicroscopic transfersome vesicles (page 147, fourth full paragraph). Paul does not specifically disclose that the number of antigen-bearing dendritic cells in a lymphoid organ are increased, however, that limitation would be inherent in the prior art method. Also, it is noted that Table 1 indicates that epicutaneous immunization with the transfersomes resulted in antic-BSA-FITC antibodies of the IgG2a isotype. This isotype is consistent with a TH1 response against the antigen and implies that activation of T-cells by antigen presenting cells substantiating the activation of dendritic cells (see Roitt et al, Immunology (text), 1993, pages 8.3-8.4). Paul et al also anticipated claim 20 as the penetration of the stratum corneum by transferosomes is equivalent to the disruption of the stratum corneum..

The rejection of claims 52 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Glenn et al (U.S. 5,980,898) is maintained for reasons of record. Claim 55 is also included in this rejection. The specific embodiments of claims 1, 2, 12, 13, 14, 28-31 and 52 are recited above. Claim 18 embodies the method of claim 1 wherein the antigen is introduced into

the mammal by a virus, bacterium, fungus or a parasite. Claim 27 embodies the method of claim 1 wherein the antigen is endogenous to the mammal and is pathologic. Claim 52 is drawn to a method for enhancing an immune response in a mammal against an endogenous antigen comprising repeated topical application to the mammal of a lipophilic compound having a molecular weight of less than or equal to 500 Daltons, wherein the lipophilic compound is applied in an amount sufficient to increase the number of antigen-bearing dendritic cells in a lymphoid organ. Claim 53 embodies the method of claim 52 wherein said endogenous antigen is a tumor antigen.

Glenn et al disclose a method for vaccinating a mammal comprising the administration of an antigen such as a tumor antigen (column 3, lines 64-67 and column 15, lines 52-67) in a composition comprising an activator of Langerhans cells, wherein said activators include trinitrochlorobenzene, dinitrofluorbenzene, pentadecylcatecol and lipid A (column 11, lines 31-40), thus fulfilling the specific embodiments of a lipophilic molecule having a molecular weight less than or equal to 500 Daltons. Glenn et al also disclose that the antigen may be derived from a pathogen that can infect the organism such as a bacterium, virus, fungus or parasite in addition to a autoantigen, thus fulfilling the specific embodiments of 18 and 27. Further, although Glenn et al do not specifically teach the further embodiments of claims 28-31 they would be inherent within the prior art method.

Applicant has not amended claims 52 or 53, but argues that Glenn does not disclose the increase the number of antigen-bearing dendritic cells in a lymphoid organ. however, this would be an inherent property of the method of Glen as the accumulation of antigen presenting cells in a lymphoid organ would result in an effective vaccination.

Claim 57 is objected to for being dependent on a rejected claim.

The rejection of claims 1, 3, 6, 8, 11, 13-19, 21-24, 27-31, 51-53 and 55-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,210,672. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '672 patent anticipate the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
9/8/03